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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,324	07/13/2001	Shizuo Akira	31671-173143	2302
26694	7590	12/09/2003	EXAMINER	
VENABLE, BAETJER, HOWARD AND CIVILETTI, LLP			QIAN, CELINE X	
P.O. BOX 34385			ART UNIT	
WASHINGTON, DC 20043-9998			PAPER NUMBER	

1636

DATE MAILED: 12/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

SM.

Advisory Action

Application No.

09/889,324

Applicant(s)

AKIRA ET AL.

Examiner

Celine X Qian

Art Unit

1636

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

SM.

THE REPLY FILED FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 1-7.

Claim(s) withdrawn from consideration: 8,9 and 12-51.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

Anne-Marie Falk
ANNE-MARIE FALK, PH.D.
PRIMARY EXAMINER

Continuation of 2. NOTE: The proposed amendment does not overcome the 112 1st paragraph rejection set forth in the final rejection (see reasons below).

Continuation of 5. does NOT place the application in condition for allowance because: The proposed amendment does not overcome the 112 1st paragraph rejection raised in the final rejection. The written description and enablement requirements are not satisfied for reasons set forth of the record mailed on 1/14/03 and 7/29/03. Although Applicants amended non-human animal to mouse, the specification only describes mice with specific genetic modification, homozygous disruption of TLR2, TLR4 or MyD88, that exhibit the phenotype of unresponsive to a lipoprotein as a bacterial cell component. The specification fails to describe any other mouse with or without genetic modification that exhibits the same phenotype. Thus the structural functional relationship between the mouse model and the disclosed phenotype is missing. Therefore, the written description requirement is not satisfied. As discussed in the office action mailed on 1/14/03, the breadth of the claim relative to the teaching of the specification is too broad. The amended claim encompasses mice with or without genetic modification that is unresponsive to bacterial cell components. The specification does not teaches how to make such mouse except TLR2, TLR4 and MyD88 knockout mouse. Considering the limited teaching of the specification and unpredictability of the art (see detailed discussion in the office action mailed on 1/14/03), one skilled in the art would have to engage in undue experimentation to make the invention in commensurate with its scope. Therefore, the invention is not enabled to its full scope.